

binding unless a party files a civil action in a district court of the United States within the time frames specified in § 423.858.

Subpart U—Reopening, ALJ Hearings, MAC review, and Judicial Review

SOURCE: 74 FR 65363, Dec. 9, 2009, unless otherwise noted.

§ 423.1968 Scope.

This subpart sets forth the requirements relating to the following:

- (a) Part D sponsors, the Part D IRE, ALJs, and the MAC with respect to reopenings.
- (b) ALJs with respect to hearings.
- (c) MAC with respect to review of Part D appeals.
- (d) Part D enrollees' rights with respect to reopenings, ALJ hearings, MAC reviews, and judicial review by a Federal District Court.

§ 423.1970 Right to an ALJ hearing.

(a) If the amount remaining in controversy after the IRE reconsideration meets the threshold requirement established annually by the Secretary, an enrollee who is dissatisfied with the IRE reconsideration determination has a right to a hearing before an ALJ.

(b) If the basis for the appeal is the refusal by the Part D plan sponsor to provide drug benefits, CMS uses the projected value of those benefits to compute the amount remaining in controversy. The projected value of a Part D drug or drugs shall include any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year.

(c) *Aggregating appeals to meet the amount in controversy* (1) *Enrollee*. Two or more appeals may be aggregated by an enrollee to meet the amount in controversy for an ALJ hearing if—

- (i) The appeals have previously been reconsidered by an IRE;
- (ii) The request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in § 423.1972(b); and
- (iii) The ALJ determines that the appeals the enrollee seeks to aggregate

involve the delivery of prescription drugs to a single enrollee.

(2) *Multiple enrollees*. Two or more appeals may be aggregated by multiple enrollees to meet the amount in controversy for an ALJ hearing if—

- (i) The appeals have previously been reconsidered by an IRE;
- (ii) The request for ALJ hearing lists all of the appeals to be aggregated and each aggregated appeal meets the filing requirement specified in § 423.1972(b); and
- (iii) The ALJ determines that the appeals the enrollees seek to aggregate involve the same prescription.

§ 423.1972 Request for an ALJ hearing.

(a) *How and where to file a request*. The enrollee must file a written request for a hearing with the entity specified in the IRE's reconsideration notice.

(b) *When to file a request*. Except when an ALJ extends the timeframe as provided in § 423.2014(d), the enrollee must file a request for a hearing within 60 calendar days of the date of the notice of an IRE reconsideration determination. The time and place for a hearing before an ALJ will be set in accordance with § 423.2020 of this chapter.

(c) *Insufficient amount in controversy*. (1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 423.1970, the ALJ dismisses the request.

(2) If, after a hearing is initiated, the ALJ finds that the amount in controversy is less than the amount required under § 423.1970, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal.

§ 423.1974 Medicare Appeals Council (MAC) review.

An enrollee who is dissatisfied with an ALJ hearing decision may request that the MAC review the ALJ's decision or dismissal as provided in § 423.2102.

§ 423.1976 Judicial review.

(a) *Review of ALJ's decision*. The enrollee may request judicial review of an ALJ's decision if—